REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-37 are pending. Claims 1, 6, 7, 8, 12, 17-19, 24-26, 29, 32, 33, 35, 36 and 37 have been amended herein.

The Amendments

Claim 1 was amended to delete the phrase "at least one of R^1 and" to remove an inconsistency as pointed out in the Office Action. Support therefor is in the specification, for example, original Claim 1.

Claim 7 was amended to correct a typographical error.

Claim 8 was amended to recite that the immunogenic carrier is a protein. Support therefor is in the specification, for example, original Claims 7 and 8.

Claims 6, 12, 17, 24 and 29 were amended to refer to enzyme labels, luminescent labels and radioisotope labels. Support therefor is in the specification, for example, the original claims and page 1, lines 18-19, and page 9, lines 4-25.

Claims 18 and 19 and 24-26 were amended in a manner similar to that for Claim 1.

Claims 32, 33, 36 and 37 were amended to refer to protein immunogenic carriers and non-poly(amino acid) immunogenic carriers. Support therefor is in the specification, for example, the original claims and page 10, lines 10-24.

Claim 35 was amended to recite that Z' is an enzyme. Support therefor is in the specification, for example, paragraph bridging pages 29-30.

Rejection under 35 U.S.C. 112

Claims 1-37 were rejected under the second paragraph of the above code section as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is believed that the amendment to Claim 1 obviates any inconsistency in that claim.

The amendment to Claim 8 obviates the rejection of that claim under the above code section.

The Office Action alleges that Claims 1, 7, 13, 18, 25 and 32-37 recite the term "immunogenic carrier", "label" and/or "acid salts" and it is not clear what "immunogenic carrier" or "label" is encompassed by the terms as immunogenic carrier may include proteins, adjuvant and other non-protein substances and label may include various labeling agent such as fluorescein, cyanine, enzymes, radioactive substance, electrophoretic tag, etc. Therefore, concludes the Office Action, it is unclear what is intended by the terms immunogenic carrier or label.

Applicant respectfully traverses this ground of rejection. The terms "immunogenic carrier" and "label" are discussed in detail in the specification, for example, page 10, lines 10-24 and page 9, line 4, to page 10, line 9. In addition, these terms are well-known to those skilled in the assay art.

Claims 1 and 7 were also rejected as indefinite because, asserts the Office Action, it is not clear what is encompassed by the term "acid salts". Applicant respectfully traverses this ground of rejection. The term "acid salts" is defined in the specification, for example, pate 8, lines 30-32. Furthermore, the term is well-known to the skilled artisan in the chemistry area.

Claims 1 7, 25 and 26 were rejected for recitation of the term "protecting group". The Office Action contends that it is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups -OH, -NH, -SH, -COOH and -CO. Therefore, concludes the Office Action, these claims are vague and indefinite for not clearly defining the protecting group.

First, the term "protecting group" is used in the claims for a substituent on either an -O- or -N- functionality. Second, the specification discusses in detail what is meant by the term. See, for example, page 16, lines 15-26. Finally, the term is well-known to those skilled in the art.

With respect to claims 26, 30, 31, 34 and 35, the Office Action alleges that it is not clear whether "antibody" used in the method is raised against a compound of what formula, i.e., against what hapten immunogen conjugate? In each of above claims, a label conjugate or an enzyme label conjugate in accordance with embodiments of the present invention is recited. Consequently, any antibody specific for the designated compound is intended to be included in the claimed methods since

the patentability of the methods is determined by the label conjugate and not the antibody. In addition, antibodies are discussed in detail in the specification, for example, page 19, line 11, to page 20, line 32.

The Office Action contends that it is not clear what is encompassed by the term "analog" in Claims 33, 36 and 37. The term "analog" is defined in the specification, for example, page 20, line 33, to page 21, line 14.

With respect to claims 17, 24 and 29, the Office Action asserts that it is not clear what is encompassed by the terms "enzyme", "luminescer" and "radioisotopes" as these are generic terms and may include a variety of enzymes, luminescers and radioisotopes. Applicant has amended the above claims to refer to enzyme labels, luminescent labels and radioisotope labels. As mentioned above, a discussion of labels is found in the specification, for example, page 9, line 4, to page 10, line 9. The use of the above as labels in assays is very well known in the art and such terms are understood by one skilled in the art.

The Office Action alleges that the term "immunogenic protein" in claims 32, 33, 36 and 37 is confusing. Applicant submits that the amendments to the above claims in this regard obviate this ground of rejection.

The Office Action also contends that it is not clear what is encompassed by the term "non-poly(amino acid) immunogenic carrier" in the above claims. The specification at page 10, lines 10-25, discusses immunogenic carriers including both poly(amino acid) (or protein) immunogenic carriers and other immunogenic carriers, which are differentiated from poly(amino acid) (or protein) immunogenic carriers.

Rejection under 35 U.S.C. 102

Claims 1-12, 15, 18-29, 31, 33 34 and 37 were rejected under 35 U.S.C. 102(a) as being anticipated by Hui, *et al.* (EP 1,340,981 A2) (Hui). The reference discloses compounds including haptens, intermediates, and immunogens that are useful in the production of antibodies specific for the methylenedioxy class of amphetamine derivatives.

Applicant submits that the above claims and claims depending therefrom are patentable over Hui. The reference does not disclose or suggest the compounds of the

present claims. In Hui, J is defined as 1-15 carbon atoms and 0-6 heteroatoms, M is selected from the group consisting of --O--, --CO--, --NR^4--, --S--, --C(=NH)O--, --NH(CO)-- --NH(CO)NH--, --NH(CS)--, --NH(CS)NH--, --O(CO)NH--, --NH(C=NH)--, and maleimidothioether, wherein R^4 is selected from the group consisting of hydrogen and an alkyl group. T is selected from the group consisting of hydrogen, a hydroxyl, a leaving group, a macromolecular carrier, and a label.

The aforementioned J-M-T moiety of the reference does not anticipate or suggest the moieties claimed in Claim 1. The disclosure of the reference provides no more than an invitation for one to invent linking groups. For example, Hui does not disclose or suggest at least the $(CH_2)_n$ of the $-C(O)(CH_2)_nR^5$, $-C(O)(CH_2)_nNHC(O)R^5$, and $-C(O)(CH_2)_nNHC(O)(CH_2)_nSR^5$ moieties. Furthermore, for example, the reference does not disclose or suggest at least the $NHC(O)(CH_2)_nS$ portion of the $-C(O)(CH_2)_nNHC(O)(CH_2)_nSR^5$ moiety or the NHC(O) portion of the $-C(O)(CH_2)_nNHC(O)R^5$ moiety. Hui does not disclose or suggest at least the $(SO_2R^5)=CH_2$ part of the $-(CH_2)_nC(SO_2R^5)=CH_2$ and $-(CH_2)_nC(SO_2R^5)=CH_2$ moieties and does not disclose or suggest at least the $SCH_2C(O)$ portion of the $-(CH_2)_nSCH_2C(O)R^5$ moiety.

For reasons much the same as those indicated above, Hui does not disclose or suggest Claim 7 and those claims depending therefrom.

Hui does not disclose or suggest the antibodies of Claim 15, which are raised against the immunogens of Claim 14, which depends from Claim 13. The compounds of Claim 13 are not disclosed or suggested by the reference, which makes no disclosure concerning substituents on the benzene ring. The Office Action asserts that the antibodies of Claim 15 are considered functionally equivalent to the antibodies of Hui, i.e., continues the Office Action, they have the same specificity. However, the antibodies of Claim 15 are raised against an immunogen that is structurally different from the immunogens of Hui. Accordingly, one skilled in the art would expect that the antibodies have different specificity in that they would recognize a different portion of the entactogen molecule.

For reasons much the same as those indicated above for the rejection of Claim 1, Hui does not disclose or suggest Claims 18, 25, 26, 31, 33, 34 and 37 and those claims depending therefrom.

Claims 1-12, 15, 18-29, 31, 33, 34 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Rouhani, *et al.* (GB 2,361,473 A) (Rouhani). Rouhani discusses ecstasy-class analogs and the use of these analogs in detection of ecstasy-class compounds. The reference discloses certain immunogens for generating antibodies and also discloses certain enzyme conjugates.

The reference does not disclose or suggest the compounds of the present claims. In Rouhani, Q is selected from the group consisting of hydrogen, a first moiety, a substituted derivative of the first moiety, and L^1_n-Z, where the first moiety is selected from the group consisting of a straight moiety, a branched moiety, a cyclic moiety, and combinations thereof, and the first moiety has a backbone of m backbone atoms where m is an integer ≥ 1, with the m backbone atoms independently selected from the group consisting of carbon, nitrogen, oxygen, sulfur, a non-substitutable halide, and combinations thereof; where L^1_n is selected from the group consisting of a second moiety and a substituted derivative of the second moiety; where the second moiety is selected from the group consisting of a straight moiety, a branched moiety, a cyclic moiety, and combinations thereof, and the second moiety has a backbone of n backbone atoms where n is an integer ≥ 0, with the n backbone atoms independently selected from the group consisting of carbon, nitrogen, oxygen, sulfur, a non-substitutable halide, and combinations thereof; and where Z is a moiety capable of chemically bonding, either directly or indirectly, with an immunogenic carrier, a detectable label, or a solid capture vehicle.

Rouhani indicates that the phrase "a linker containing at least one carbon atom" is meant to refer to any generic linking group between two other groups, e.g., a linker between hapten and protein, or a linker between hapten and a functional group suitable for attachment to another molecule, which contains at least one carbon atom. The linker group may be a C_1-C_{20} hydrocarbon chain containing zero to ten heteroatoms selected from the group consisting of N, O, and S, and which contains at least as many carbon atoms as heteroatoms. Examples of such generic linking groups include --O--$(CH_2CH_2O)_n$--, where n is an integer between 1 and 10 (i.e., a polyethylene glycol linker); --CH_2CH_2-phenyl-CH_2CH_2-- (in ortho, meta, or para connection); --CH_2CH_2--CONH--CH_2CH_2-- (i.e., an amide linkage), --C(=O)--CHS--NH-- (i.e., an amino acid linker, where S is a naturally or non-naturally occurring amino acid side chain) or any

straight-chain, branched, cyclic, or combination of straight-chain, branched, or cyclic linking group that will serve as a covalent linkage between the two other groups. A further example in the reference is C_1-C_{20} alkyl groups.

The aforementioned generic recitation of a group of atoms selected from the group of atoms set forth in the reference does not anticipate or suggest the moieties claimed in Claim 1. The disclosure of the reference is no more than an invitation for one to invent linking groups. Furthermore, the specific disclosure of Rouhani of certain linking groups does not include those in the present claims. For example, Rouhani does not disclose or suggest at least the $(CH_2)_n$ of the $-C(O)(CH_2)_nR^5$, $-C(O)(CH_2)_nNHC(O)R^5$, and $-C(O)(CH_2)_nNHC(O)(CH_2)_nSR^5$ moieties. Furthermore, for example, the reference does not disclose or suggest at least the $NHC(O)(CH_2)_nS$ portion of the $-C(O)(CH_2)_nNHC(O)(CH_2)_nSR^5$ moiety or the NHC(O) portion of the $-C(O)(CH_2)_nNHC(O)R^5$ moiety. Rouhani does not disclose or suggest at least the $(SO_2R^5)=CH_2$ part of the $-(CH_2)_nC(SO_2R^5)=CH_2$ and $-(CH_2)_nC(SO_2R^5)=CH_2$ moieties and does not disclose or suggest at least the $SCH_2C(O)$ portion of the $-(CH_2)_nSCH_2C(O)R^5$ moiety.

For reasons much the same as those indicated above, Rouhani does not disclose or suggest Claim 7 and those claims depending therefrom.

Rouhani does not disclose or suggest the antibodies of Claim 15, which are raised against the immunogens of Claim 14, which depends from Claim 13. The compounds of Claim 13 are not disclosed or suggested by the reference, which makes no disclosure concerning substituents on the benzene ring. The Office Action asserts that the antibodies of Claim 15 are considered functionally equivalent to the antibodies of Rouhani, i.e., continues the Office Action, they have the same specificity. However, the antibodies of Claim 15 are raised against an immunogen that is structurally different from the immunogens of Rouhani. Accordingly, one skilled in the art would expect that the antibodies have different specificity in that they would recognize a different portion of the entactogen molecule.

For reasons much the same as those indicated above for the rejection of Claim 1, Rouhani does not disclose or suggest Claims 18, 25, 26, 31, 33, 34 and 37 and those claims depending therefrom.

Conclusion

Applicant has demonstrated that Claims 1-12, 15, 18-29, 31, 33, 34 and 37 satisfy the requirements of 35 U.S.C. 112 and 102. Claims 13, 14, 16, 17, 30, 32 and 35-36 satisfy the requirements of 35 U.S.C. 112 and were not rejected over the art. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

Theodore J. Leitereg
Attorney for Applicant
Reg. No. 28,319

Theodore J. Leitereg
31420 Pennant Ct.
Temecula CA 92591
(602) 369-1751